

REMARKS

I. Incorporation by Reference of Prior Arguments

By way of this Response, Applicants re-assert and incorporate by reference their prior arguments before the Office, including those arguments made in the responses submitted on October 8, 2008, March 26, 2008, and March 24, 2009.

III. Claims

Claims 1-10 are currently pending and stand rejected. By way of this Response, Claim 1 has been amended. No new matter is presented by way of this amendment. Support for the amendment can be found throughout the specification, including at page 6, lines 4-13 and page 8, lines 19-25 of the specification.

IV. Summary of the June 18, 2009 Office Action

In the June 18, 2009 Office Action, the Office set forth the following rejections:

- (a) Claims 1-3, 5, and 10 were rejected under 35 U.S.C. 102 (b) as being anticipated by, or in the alternative, under 35 U.S.C. 103 (a) as being obvious over U.S. Patent No. 4,632,267 ("Fowles");
- (b) Claim 4 was rejected under 35 U.S.C. 103(a) over Fowles in view of U.S. Patent No. 5,494,170 ("Burns");
- (c) Claims 6 and 9 were rejected under 35 U.S.C. 103(a) over Fowles in view of U.S. Patent No. 6,364,143 ("Knierbein"); and
- (d) Claims 7 and 8 were rejected under 35 U.S.C. 103(a) over Fowles in view of Knierbein, further in view of U.S. Patent No. D456,507 ("LeMarr").

V. The Rejection Under 35 U.S.C. § 102 Over Fowles Should Be Withdrawn.

The Office rejected Claims 1-3, 5, and 10 as anticipated under 35 U.S.C. § 102 over Fowles. To establish anticipation, the Federal Circuit has stated that it "requires the disclosure in a single prior art reference of each element of the claim under consideration." *W.L. Gore & Assocs. v. Garlock*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983); *see also* MPEP § 2131. It is not enough, however, that the prior art reference disclose all the claimed elements in isolation.

Rather, “anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim.” *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452 (Fed. Cir. 1984). Furthermore, “[t]he identical invention must be shown in as complete detail as contained in the...claim.” *Richardson v. Suznki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989).

Applicants respectfully submit that a case for anticipation has not been established as Fowles fails to disclose each and every element of Claim 1. As amended, Claim 1 is directed to a connector which can accommodate a rod or spike for filing or withdrawal, comprising an elastically deformable pinching-off part with a noncircular axial cross-section that is different in two mutually perpendicular directions, which can be pinched with a pinching device.

In contrast, Fowles teaches a connecting part with a circular axial cross section. Fowles does not describe a connecting part with a noncircular axial cross section that is different in two mutually perpendicular directions such that the cross section can be pinched with relatively minimal force.

As such, Fowles fails to disclose each and every element of independent Claim 1. Accordingly, as Claims 2-3, 5, and 10 depend from independent Claim 1, Fowles fails to disclose each and every element of Claims 2-3, 5, and 10. Applicants respectfully request the rejection under 35 U.S.C. § 102 based upon Fowles be withdrawn.

VI. The Rejections Under 35 U.S.C. § 103 Should Be Withdrawn.

The Office rejected dependent Claim 4, which depends from independent Claim 1, as obvious under 35 U.S.C. § 103 over Fowles in view of Burns. The Office also rejected dependent Claims 6 and 9, which depend from independent Claim 1, as obvious under 35 U.S.C. § 103 over Fowles in view Knierbein. The Office further rejected dependent Claims 7 and 8, which depend from independent Claim 1, as obvious under 35 U.S.C. § 103 over Fowles in view of Knierbein and LeMarr. The Applicants respectfully submit that no *prima facie* case of obviousness has been established because the Office has not demonstrated that the references, regardless if combined, teach or suggest all of the limitations of the claimed invention.

To establish a *prima facie* case of obviousness, three basic criteria must be met. M.P.E.P. § 2143. First, there must an apparent reason why a person of ordinary skill would have combined the prior art elements in the manner claimed. *KSR Int'l v. Teleflex, Inc.*, 127 S.Ct.

1727, 1741 (2007). Second, there must be a reasonable expectation of success. *See* Exam. Guidelines for Determining Obviousness Under 35 U.S.C. 103 in view of *KSR Int'l Co. v. Teleflex, Inc.*, 72 Fed. Reg. 57530 (Oct. 10, 2007). Third, the references, when combined, must teach or suggest all the claim limitations or the Office must explain why the shortcomings of the prior art would have been obvious. *Id.* at 57528.

The burden of establishing a *prima facie* case of obviousness lies with the PTO. In determining obviousness, one must focus on the invention as a whole. *Symbol Technologies Inc. v. Opticon, Inc.*, 935 F.2d 1569, 1577-78 (Fed. Cir. 1991). The primary inquiry is: “[w]hether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have had a reasonable likelihood of success ... Both the suggestion and the expectation of success must be found in the prior art, not the applicant’s disclosure.” *In re Dow Chemical*, 837 F.2d 469, 473, 5 U.S.P.Q. 2d 1531 (Fed. Cir. 1988).

Fowles fails to teach or suggest each and every element of independent Claim 1. Specifically, Fowles fails to teach a connecting part with a noncircular axial cross section that is different in two mutually perpendicular directions such that the cross section can be pinched with relatively minimal force. Moreover, Fowles actually teaches away from the present claims, as Fowles teaches a connector that is sealed during construction. Fowles describes a closure part that is “overmolded” to the connecting part port during construction such that once it is removed, it “prevent[s] the closure from being easily reinserted into the port.” (Fowles 1:64-2:5). Thus, because the closure part is molded onto the connecting part during construction, and the closure part cannot be reinserted onto the connecting part once it has been removed, the bag can only be filled with liquid after the closure part has already been attached to the connecting part.

By contrast, the present invention does not teach a closure part and a connector part which must be attached to each other during construction. Instead, the present invention teaches a closure part which is inserted onto the connecting part *after* the bag has been constructed, filled with liquid, and pinched. (*See* Appl. at 2:29-29; 8:19-28.) Thus, the present invention has the added benefit of allowing the bag to be filled with liquid after its construction, such that the bags are light and do not take up much space when they are transported to a hospital or medical facility where they will be filled with liquid and used.

Fowles also teaches that the closure part and connector part must be constructed of different materials, such that they are incompatible with each other so that they “will not cross-

link and seal together” during construction. (Fowles 4:32-37). By contrast, the present invention claims no such limitation. (*See* Appl. at 3:7.) Therefore, construction of the present invention is simpler, cheaper, and easier, as there is no requirement that the closure part and connector part be of different materials.

Furthermore, Fowles teaches a tamper evident closure that allows a user to know when the connector part’s seal has been broken and fluids have been withdrawn. (Fowles 1:46-52, 3:37-40). To this end, once a user has inserted a spike or rod to withdraw fluids through the connector part, Fowles teaches that the connector part cannot be resealed, so as to prevent tampering. (Fowles 1:64-2:5) By contrast, the present invention provides for a self sealing membrane in the connector part, so that once the user is finished withdrawing liquids and removes the spike or rod, the connector automatically reseals. (*See* Appl. at 9:4-6.) This has the added benefit of preventing liquids from escaping the bag once the spike or rod is removed, permitting a user to withdraw liquids multiple times from same the bag, and allowing a user to save a bag with liquid remaining for later use.

The deficiencies of Fowles are not cured by Burns, LeMarr, or Knierbein. The Office does not cite Burns, LeMarr, or Knierbein in support of a rejection of independent Claim 1. Rather the Office cites these references in support of rejecting dependent Claims 4 and 6-9, all of which are dependent on independent Claim 1. The Office submits that Burns teaches a snap fit and a self-sealing membrane. The Office also submits that LeMarr teaches a nebulizer vial comprising an arrow designed as a recess and/or as a raised structure that shows the user where the fluid will exit the container when opened. Additionally, the Office submits that Knierbein teaches a flat grip piece connector which can be broken off and a base part designed in the shape of a boat. Finally, the Office submits that it would have been obvious for one of ordinary skill in the art to combine the teachings of Fowles with Burns, LeMarr, or Knierbein.

As such, one of ordinary skill in the art, when reading Fowles in view of Burns, LeMarr, or Knierbein would not be taught or suggested to develop a connecting part that could accommodate a closure part after filling the bag. Additionally one of ordinary skill in the art, when reading Fowles in view of Burns, LeMarr, or Knierbein would not be taught or suggested that the connecting part and closure part could be constructed of the same materials. Therefore, even if Fowles were combinable with Burns, LeMarr, or Knierbein, which the Applicants deny, Applicants submit that such a combination fails to teach or suggest all the elements of

independent Claim 1. The Applicants further submit that Claims 2-3, 5, and 10 are patentable over Fowles, alone or in combination with Burns, LeMarr, or Knierbein. Claims 2-3, 5, and 10 depend on independent Claim 1. Accordingly, the patentability of independent Claim 1 establishes the patentability of dependent Claims 2-3, 5, and 10. Therefore, the Applicants respectfully request that the rejection of Claims 2-3, 5, and 10 under 35 U.S.C. § 103(a) be withdrawn. The patentability of independent Claim 1 also establishes the patentability of Claims 4 and 6-9. Accordingly, the Applicants respectfully request that the rejection of Claims 4-9 under 35 U.S.C. § 103(a) be withdrawn.

Based on the above, the Applicants respectfully submit that the Office's remaining rejections under 35 U.S.C. § 103 over the cited references are not supported and be withdrawn, including the rejections of Claim 4 over Fowles in view of Burns; Claims 6 and 9 over Fowles in view of Knierbein; and Claims 7 and 8 over Fowles in view of Knierbein and LeMarr.

CONCLUSION

For at least the foregoing reasons, it is respectfully submitted that Claims 1-10 are in condition for allowance. Early and favorable consideration is respectfully requested, and the Examiner is encouraged to contact the undersigned with any questions or to otherwise expedite prosecution.

Further, none of Applicants' amendments or cancellations are to be construed as dedicating any such subject matter to the public, and Applicants reserve all rights to pursue any such subject matter in this or a related patent application.

Respectfully submitted,

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